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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/720,510	11/24/2003	Richard D. Gresham	2877	4596

7590 03/18/2008
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EXAMINER

MENDOZA, MICHAEL G

ART UNIT	PAPER NUMBER
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3734

MAIL DATE	DELIVERY MODE
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03/18/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/720,510	Applicant(s) GRESHAM ET AL.	
	Examiner MICHAEL G. MENDOZA	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 November 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-26 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-26 have been considered but are moot in view of the new ground(s) of rejection.
2. The finality of the action of 9/18/2007 is withdrawn.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 7 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
5. Claim 7 recites the limitation "the introducer" in lines 1 and 2. There is insufficient antecedent basis for this limitation in the claim.
6. Claim 15 recites the limitation "the introducer" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

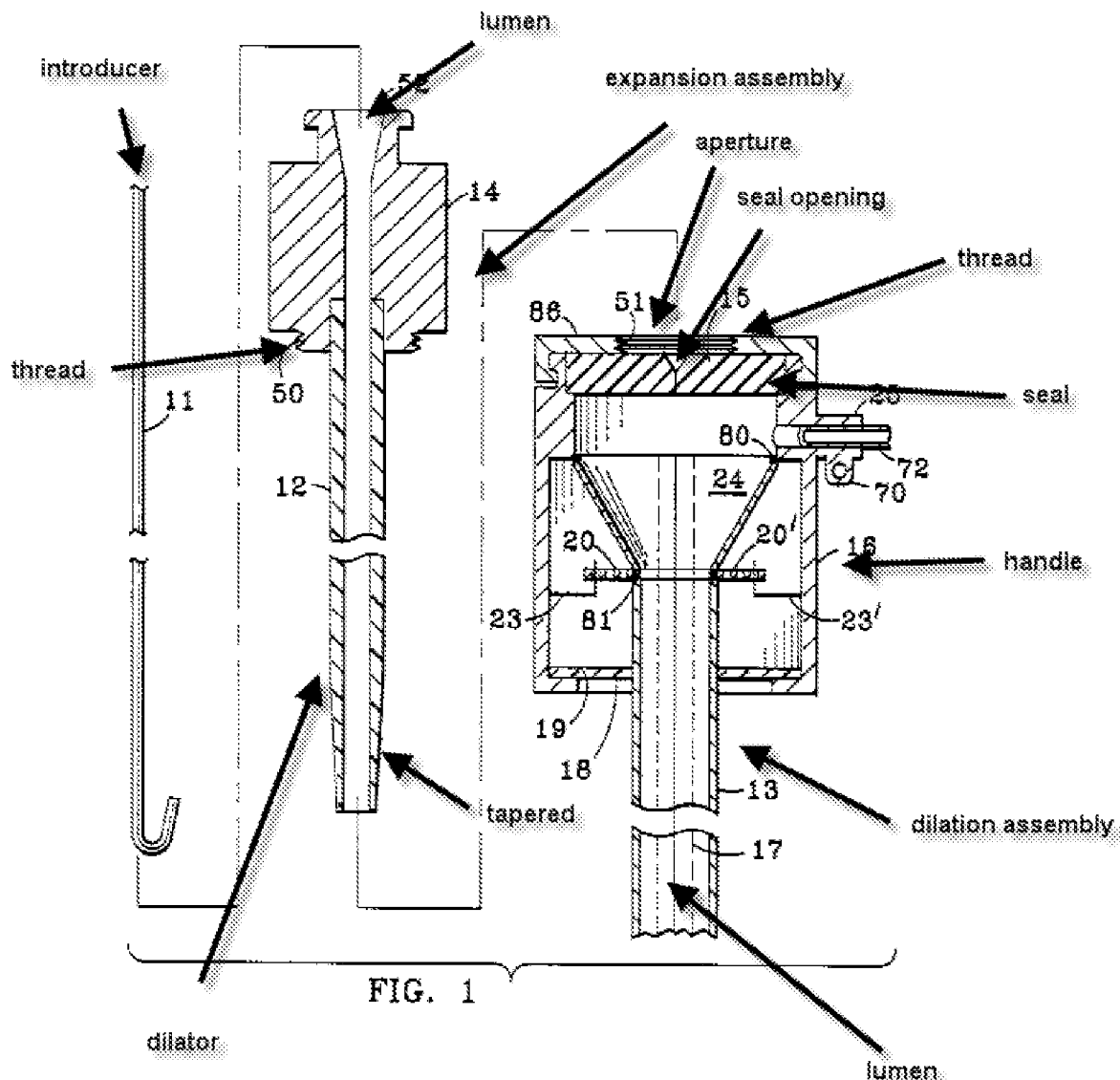
A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1-3, 7-9, 11, 12, 17-20, and 23-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Delago 5827227.

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9. Delago teach a sheath system for enabling access through an opening in the body of a patient, the sheath system comprising: a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-section area when in a non-expanded condition, a handle assembly, the handle assembly defining an aperture formed therein, and a first thread defined on the handle in the aperture thereof, an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-section area of the tubular sheath of the dilation assembly and having an outer surface defining a second thread, the second thread being arranged for engaging the first thread; an introducer sized for receipt in the lumen of the radially expandable sheath; wherein the tubular member of the expansion assembly is configured and dimensioned to be removably received within the aperture formed in the handle assembly; wherein the shaft of the introducer is removably receivable within the lumen of the tubular sheath; wherein the distal advancement of the tubular member of the expansion assembly results in radial expansion of the tubular sheath; a seal at the proximal end of the expansion assembly; a dilator; wherein a distal end of the dilator is tapered.



Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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11. Claims 1-9, 11, 12, 14, and 16-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul et al. 6080174 in view of Delago.

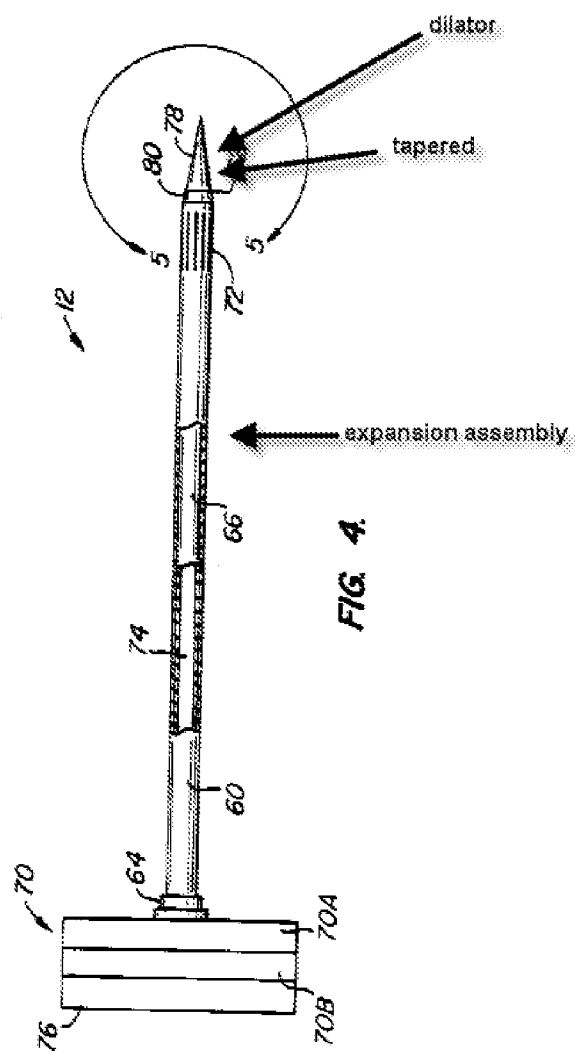
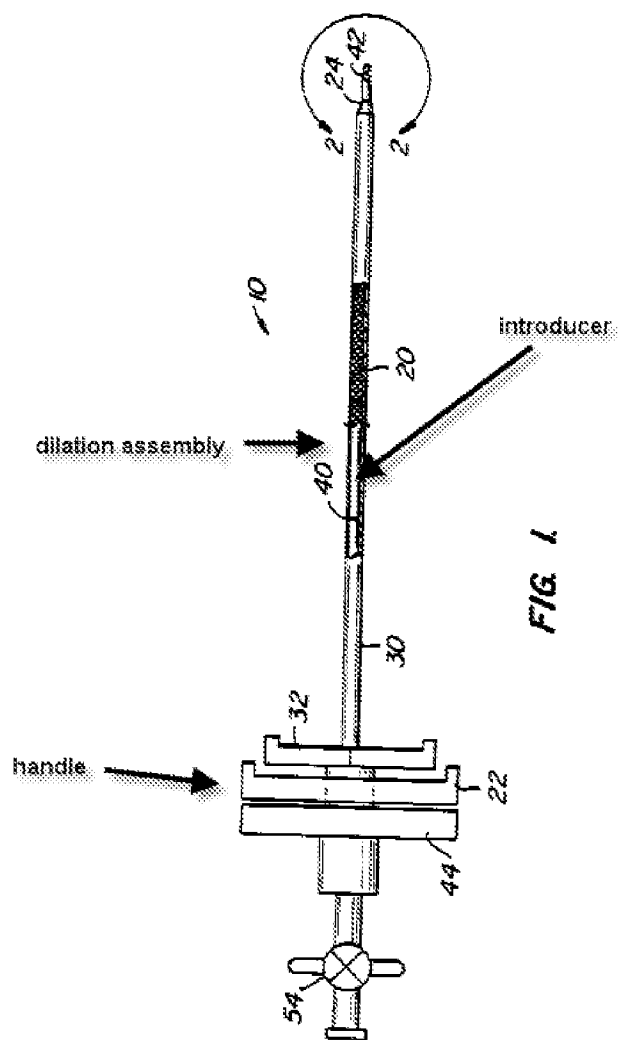
12. Dubrul et al. teaches Delago teach a sheath system for enabling access through an opening in the body of a patient, the sheath system comprising: a dilation assembly having a radially expandable tubular sheath defining a lumen having a first cross-section area when in a non-expanded condition, a handle assembly , the handle assembly defining an aperture formed therein; and an expansion assembly including a tubular member defining a lumen having a second cross-sectional area which is larger than the first cross-section area of the tubular sheath of the dilation assembly. It should be noted the Dubrul et al. fails to teach first and second threads.

13. Delago teaches a device a system using common first and second thread for attaching separate components of the system together (col. 4, lines 4-9). Therefore it would have been obvious to combine the first and second threads of Delago with the sheath system of Dubrul et al. to securely engage the dilation assembly with the expansion assembly and prevent pre-mature separation.

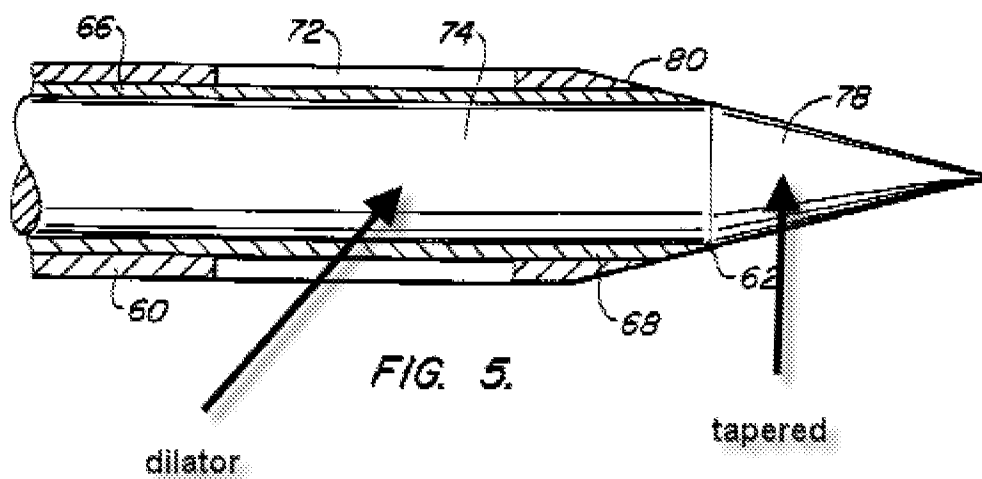
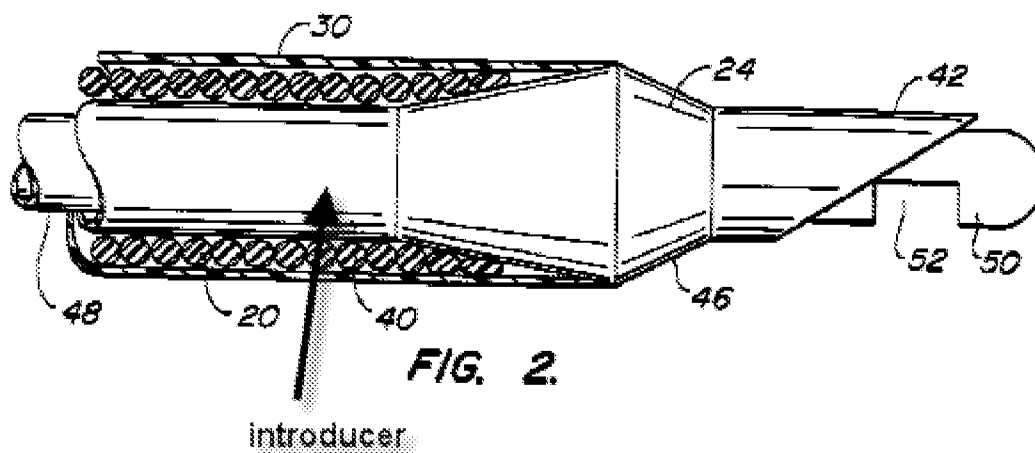
14. Dubrul/Delago teaches the sheath system according to claim 1; further comprising an introducer sized for receipt in the lumen of the radially expandable sheath; wherein the tubular member of the expansion assembly is configured and dimensioned to be removably received within the aperture formed in the handle assembly; wherein the tubular sheath of the dilation assembly comprises a mesh of individual filaments; wherein the filaments are elastic so that radial expansion of the tubular sheath causes axial shorting of the tubular sheath causes axial shortening of the

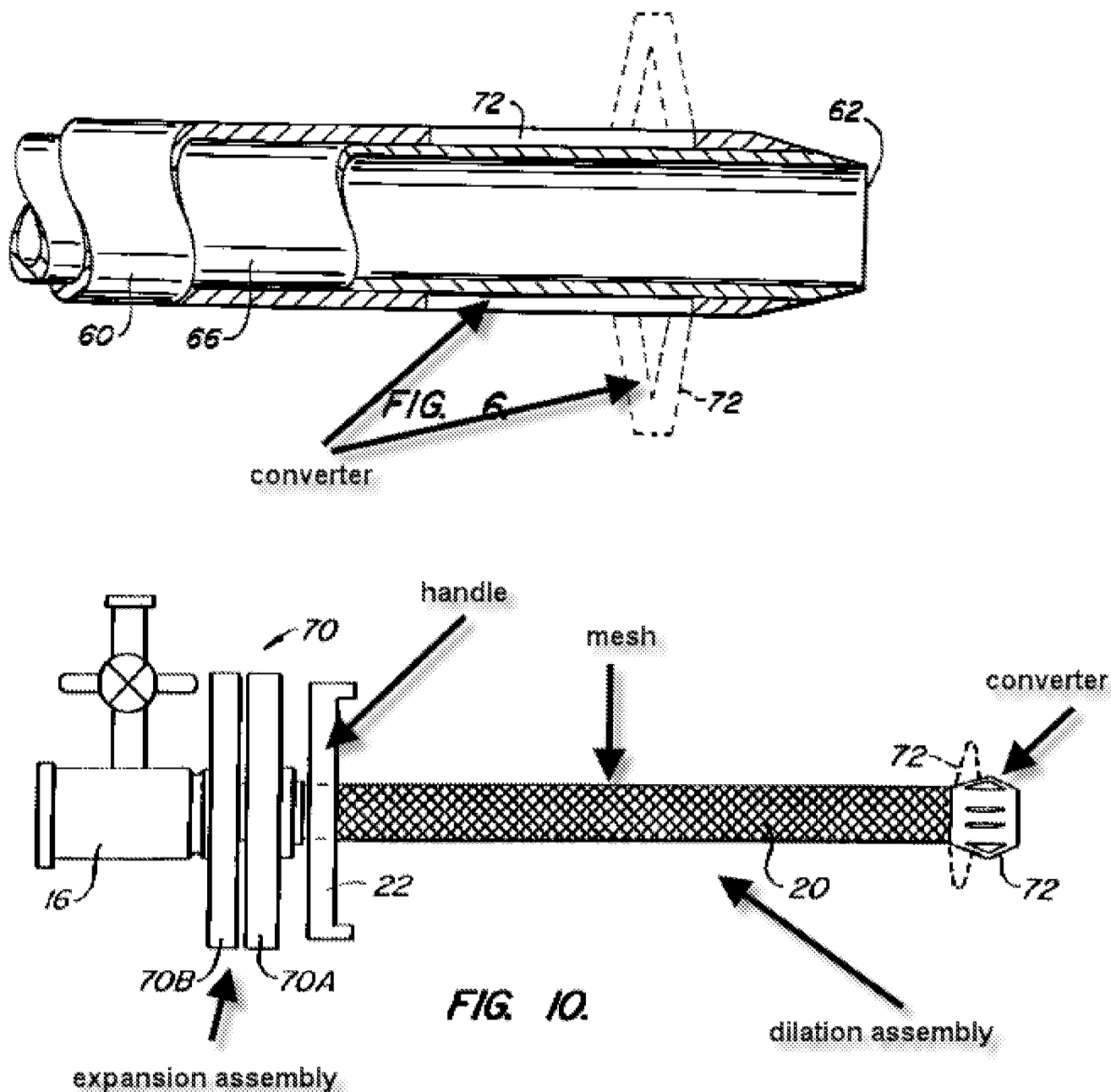
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tubular sheath; wherein the tubular sheath comprises a tubular braid of individual filaments; wherein the shaft of the introducer is removably receivable within the lumen of the tubular sheath; wherein the distal advancement of the tubular member of the expansion assembly results in radial expansion of the tubular sheath; seal at the proximal end of the expansion assembly (as taught by Delago); a dilator; wherein a distal end of the dilator is tapered; wherein the dilator has a length such that when the dilator is received with the lumen of the tubular member, the tapered distal end thereof extends beyond a distal end of the tubular member (col. 8, lines 34-38); and a converter.



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15. Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Delago or the combination of Dubrul/Delago.

16. The above references disclose the claimed invention except for wherein the seal is made from at least one of an elastomeric polymeric material and polyisoprene. It

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would have been obvious to one having ordinary skill in the art at the time the invention was made to use the claim materials, since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use a matter of obvious design choice. *In re Leshin* , 125 USPQ 416.

Therefore it would have been obvious to one having ordinary skill in the art to use an elastomeric polymeric material and polyisoprene as a matter of design choice, since Delago has broadly disclosed an elastic seal (col. 4, lines 12-14).

17. Claim 13 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dubrul/Delago as applied to the 103(a) claim rejection above, and further in view of Frova et al. 6767355.

18. Dubrul/Delago teaches the sheath system according to claim 12. However, Dubrul/Delago fails to teach wherein the distal end of the dilator defines threads.

19. Frova et al. teaches a dilator with common threads at the distal end for anchoring in tissue (col. 2, lines 38-40). Therefore it would have been obvious to one having ordinary skill in the art to include the threaded distal end of Frova et al in the device of Dubrul/Delago to secure the dilator to tissue to prevent unwanted movement.

Contacts

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL G. MENDOZA whose telephone number is (571)272-4698. The examiner can normally be reached on Mon.-Fri. 9:00 a.m. - 5:00 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. G. M./

Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3731